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| APPLICATION NO.   | FILING DATE           | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |  |
|---|-----------------------|----------------------|---------------------|------------------|--|
| 10/516,292  | 07/05/2005            | Susumu Muto          | P26318              | 5595             |  |
| 7055 7590 04/20/2007<br>GREENBLUM & BERNSTEIN, P.L.C.<br>1950 ROLAND CLARKE PLACE<br>RESTON, VA 20191 |                       |                      | EXAM                | EXAMINER         |  |
|   |                       |                      | RAE, CHARLESWORTH E |                  |  |
|   |                       |                      | ART UNIT            | PAPER NUMBER     |  |
|   |                       |                      | 1614                |                  |  |
|   |                       |                      |                     |                  |  |
| SHORTENED STATUTOR  | RY PERIOD OF RESPONSE | NOTIFICATION DATE    | DELIVERY MODE       |                  |  |
| 31 E  | DAYS                  | 04/20/2007           | ELECTRONIC          |                  |  |

# Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Notice of this Office communication was sent electronically on the above-indicated "Notification Date" and has a shortened statutory period for reply of 31 DAYS from 04/20/2007.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

gbpatent@gbpatent.com pto@gbpatent.com

|  | Application No.       | Applicant(s)                        |  |  |  |  |
|--|-----------------------|-------------------------------------|--|--|--|--|
| Office Action Commence   | 10/516,292            | MUTO ET AL.                         |  |  |  |  |
| Office Action Summary  | Examiner              | Art Unit                            |  |  |  |  |
|  | Charleswort Rae       | 1614                                |  |  |  |  |
| The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply   |                       |                                     |  |  |  |  |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). |                       |                                     |  |  |  |  |
| Status   | •                     |                                     |  |  |  |  |
| 1) Responsive to communication(s) filed on <u>08 De</u>  | ecember 2004.         |                                     |  |  |  |  |
| 2a) ☐ This action is <b>FINAL</b> . 2b) ☒ This action is non-final.  |                       |                                     |  |  |  |  |
| 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is   |                       |                                     |  |  |  |  |
| closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.  |                       |                                     |  |  |  |  |
| Disposition of Claims  |                       |                                     |  |  |  |  |
| •  |                       |                                     |  |  |  |  |
| 4) Claim(s) 1-11 is/are pending in the application.  |                       |                                     |  |  |  |  |
| 4a) Of the above claim(s) is/are withdrawn from consideration.  5) ☐ Claim(s) is/are allowed.  |                       |                                     |  |  |  |  |
| 6) Claim(s) is/are rejected.   | <b>.</b>              |                                     |  |  |  |  |
| 7) Claim(s) is/are objected to.  | •                     |                                     |  |  |  |  |
| 8) Claim(s) 1-11 are subject to restriction and/or e   | election requirement. |                                     |  |  |  |  |
|  |                       |                                     |  |  |  |  |
| Application Papers   |                       |                                     |  |  |  |  |
| 9) The specification is objected to by the Examiner.   |                       |                                     |  |  |  |  |
| 10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner.   |                       |                                     |  |  |  |  |
| Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  |                       |                                     |  |  |  |  |
| Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.   |                       |                                     |  |  |  |  |
| · · ·  |                       |                                     |  |  |  |  |
| Priority under 35 U.S.C. § 119   |                       |                                     |  |  |  |  |
| 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  |                       |                                     |  |  |  |  |
| a) All b) Some * c) None of:   |                       |                                     |  |  |  |  |
| 1. Certified copies of the priority documents have been received.  |                       |                                     |  |  |  |  |
| 2. Certified copies of the priority documents have been received in Application No   |                       |                                     |  |  |  |  |
| 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  |                       |                                     |  |  |  |  |
| * See the attached detailed Office action for a list of the certified copies not received.   |                       |                                     |  |  |  |  |
| See the attached detailed Office action for a list of the certified copies not received.   |                       |                                     |  |  |  |  |
|  |                       |                                     |  |  |  |  |
|  | •                     |                                     |  |  |  |  |
| Attachment(s)  | •                     |                                     |  |  |  |  |
| 1) Notice of References Cited (PTO-892)  | 4) Interview Summary  |                                     |  |  |  |  |
| 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  3) Information Disclosure Statement(s) (PTO/SB/08)  Paper No(s)/Mail Date  5) Notice of Informal Patent Application   |                       |                                     |  |  |  |  |
| Paper No(s)/Mail Date  | 6) Other:             | 11                                  |  |  |  |  |
| U.S. Patent and Trademark Office   | tion Cumman:          | nd of Donor No (Mail Date 20070406  |  |  |  |  |
| PTOL-326 (Rev. 08-06) Office Ac  | tion Summary Pa       | art of Paper No./Mail Date 20070406 |  |  |  |  |

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#### **DETAILED ACTION**

### Status of the Claims

Claims 1-11 are currently pending in the instant application and are the subject of the Office action.

## Election of Species

## Election of Species regarding Groups I and II

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1. Specifically, the claims encompass multiple species of chemical compounds and cancers.

Applicant is required to elect a single specific compound for

With respect to multiple species of compounds encompassed by the instant generic invention, each chemical compound represents a different chemical entity and reasonably exhibit different pharmacologic and pharmaceutical characteristics. To the extent that different chemical compounds would reasonably exhibit different treatment effects depending on the targeted cancer, these species do not relate to a single general inventive concept. Also, cancers exhibit different morphologic, etiologic, clinical characteristics, and therapeutic responsiveness to the same or different therapy. To the extent that the therapeutic responsiveness of different cancer species is not reasonably predictable, these species do not relate to a single general inventive concept. Thus, the election requirement is proper as the above species lack unity of invention.

Applicant is required to elect for purposes of examination the following:

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a) a single specifically disclosed chemical species wherein each and every variable or optional group is specifically defined e.g. 5-chloro-2-hydroxy-N-[4-(2,3,4,5,6-pentafluorophenyl)-thiazol-2-yl]benzamide (please note this example is cited for illustrative purposes only and is not intended in any way to suggest or recommend the election of a particular compound; see also specification, page 192, line 11); and

b) a single specific cancer species e.g. breast cancer.

Applicant is required under 35 USC 121 to <u>elect a single disclosed specie</u> for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 1 is considered to be generic to the above species.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an

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allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charlesworth Rae whose telephone number is 571-272-6029. The examiner can normally be reached between 9 a.m. to 5:30 p.m. Monday to Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, can be reached at 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent

Application Information Retrieval (PAIR) system. Status information for published applications

may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http:pair-direct.uspto.gov. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 800-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

6 April 2007 CER

> BRIAN-YONG S. KWON PRIMARY EXAMINER